PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 16647-WO-03	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/IL2004/000961	International filing date *(day/month/year)* 21.10.2004	Priority date *(day/month/year)* 22.10.2003
International Patent Classification (IPC) or national classification and IPC A61P19/10, A23L1/29, A23D9/00, C11C3/10, A23C11/00, A23L1/30		
Applicant ENZYMOTEC LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 10 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☒ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
21.08.2005	07.02.2006
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Groh, B Telephone No. +49 89 2399-7855

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL2004/000961

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

   Description, Pages

   1-20 as originally filed

   Claims, Numbers

   1-12 received on 23.08.2005 with letter of 22.08.2005

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☒ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☒ the claims, Nos. 13-15
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IL2004/000961

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	
	No:	Claims	1-12
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-12
Industrial applicability (IA)	Yes:	Claims	1-12
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

Reference is made to the following documents:

D1: DATABASE MEDLINE [Online] US NATIONAL LIBRARY OF MEDICINE (NLM), BETHESDA, MD, US; 15 November 1997 (1997-11-15), CADOGAN J ET AL: "Milk intake and bone mineral acquisition in adolescent girls: randomised, controlled intervention trial." XP002315046 Database accession no. NLM9390050

D2: DATABASE MEDLINE [Online] US NATIONAL LIBRARY OF MEDICINE (NLM), Bethesda, MD, US; October 2003 (2003-10), VOLEK JEFF S ET AL: "Increasing fluid milk favorably affects bone mineral density responses to resistance training in adolescent boys." XP002315047, Database accession no. NLM14520257

D3: DATABASE EMBASE [Online] ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL; 2000, GUEGUEN L: "Calcium balance: Requirements, intake and bioavailability" XP002315048, Database accession no. EMB-2000369954

D4: DATABASE EMBASE [Online] ELSEVIER SCIENCE PUBLISHERS, AMSTERDAM, NL; 1 September 2003 (2003-09-01), SCHOLZ-AHRENS K E: "Nutrients of milk and their relevance for health" XP002315049, Database accession no. EMB-2003380690

D5: EP-A2-1 252 824 (ABBOTT LABORATORIES) 30 October 2002 (2002-10-30)

D6: US-A-5 709 888 (GIL ET AL) 20 January 1998 (1998-01-20)

D7: DATABASE FSTA [Online] INTERNATIONAL FOOD INFORMATION SERVICE (IFIS), FRANkFURT-MAIN, DE; 1996, ANONYMOUS: "Betapol, a breakthrough in infant formula fats." XP002315600, Database accession no. 96-1-08-n0030

D8: "Enzymotec launches InFat - perfect fat for infant formulas" [Online] 4 July 2003 (2003-07-04), XP002315599, Retrieved from the Internet: <URL:www.foodingredientsfirst.com/newsmaker > [retrieved on 2005-01-27]

1 Amendments

1.1 The applicant filed amended claims.
The basis for "... does not cause loss (of energy intake by infants and children" (underline added) in claim 9 is not apparent from the application as originally filed.
The current statement is broader than the disclosure "enhancement of energy intake

by infants and children" (p. 14 of description), because it now also comprises a 'neutral' (no loss, no gain) energy intake.

Present claim 9 does not fulfil the requirement of Art. 41(2) PCT.

1.2 Present product claim 10 is defined by reference to the use-type claim 1.
It is not clear which **use**-related features are or are not part of the **product** claim 10 (clarity Art. 6 PCT). Product-type claims have to be defined by product features.

Product claim 1 should be written as independent claim, without the reference to another claim.

1.3 Present use-type claim 12 is defined by a lipid ingredient specified in use-type claim 1.
It is not clear how the use of *a dietary ingredient for the preparation of food for infants or children* is (or is not ?) part of the use *of a lipid ingredient as a carrier for dietary substances* ?

The requirements of Art. 6 PCT are not fulfilled for present claim 12.
Claim 12 should be written as independent claim, without reference to another claim.

2 **Novelty** (Art. 33(2) PCT)

2.1 Novelty in view of bovine milk for human consumption

Applicant's argumentation was viewed. The effect shown in Exhibit A (Jacobsen R., 2005), that additional dietary calcium intake can increase the fecal fat and energy excretion, is acknowledged.

However, there is a significant difference between the uptake of *additional* dietary calcium (which may react to form calcium fatty acid soaps), and calcium bound and generally protected (casein micelles) in bovine milk or bovine milk products.
Therefore the examiner follows the opinion stated in D3, that "saturated lipids [in

bovine milk] do not interfere with calcium absorption ...".

The examiner keeps the previously raised objection:

Bovine milk (incl. bovine milk fat) is traditionally used as dietary ingredient in the preparation of food or beverages for infants and children.

Bovine milk or other bovine milk fat containing products naturally help the mineral absorption of, for example, calcium (which is present in the milk) in calves, and if consumed by humans, in them as well.

The lipids in bovine milk or bovine milk products for human consumption can be considered to be a mimetic of human milk fat (see also point "clarity" below), also bovine milk fat comprises a large amount of MCT.

Bovine milk contains calcium, magnesium and other divalent ions. Bovine milk also contains milk proteins (whey protein), phospholipids and other components, which are very efficient emulsifiers (keeping the fat in the milk emulsified).

Furthermore, it is known that bovine milk consumption is a major source of calcium, and calcium is essential for bone mineralisation and bone health. Sufficient calcium is essential as prevention of osteoporosis (= "prevention of disorders associated with depletion of bone calcium") see, for example D1, D2, D3 or D4. Consequently bovine milk consumption (or related dairy products) is considered "useful" in the prevention of disorders associated with depletion of bone calcium and/or osteoporosis and/or bone formation.

Bovine milk consumption (or related milk products) by infants and children does not cause a loss of energy intake in them, at the contrary, bovine milk consumption supplies energy to them via fat, carbohydrates and protein.

Infant and children food products (such as cereals etc.) are often prepared by combination with (bovine) milk.

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-11 is not new in the sense of Article 33(2) PCT.

2.2 It is state of the art (often even required by law) that infant formula (= food article for infants) is enhanced in Vitamins, both fat- and water-soluble.
It is the fat phase (dietary ingredient) of infant formula, which is regularly used as a carrier/solvent for the fat-soluble Vitamins added to infant formula.

Furthermore, most infant formula is based on vegetable or plant derived fat (which is one of the lipid sources in claim 1, to which claim 12 is related to).

The use of a lipid ingredient as defined in present claim 12 as a carrier for dietary supplements is not new over the prior art.

2.3 Novelty in view of D5

Note: The applicant's argumentation was viewed: It is noted that present claim 1 is formulated "... said lipid is selected from the group ...", and that "oils mimicking the triglyceride composition of human mother's milk fat" is (only) one option among other alternatives, such as "vegetable- and plant derived ... oils", which is the option relevant in the comparison to prior art D5.

Document D5 (EP1252824) discloses a method for increasing bone minerali-zation and the related nutritional components (specifically fat and calcium). The nutritional infant formula (see D5, claim 9) consists of vegetable, plant oils and of MCT oil. Added emulsifiers (mono- and diglycerides) and calcium (via condensed skimmed milk and calcium carbonate) and other minerals are disclosed in example 1 of D5.

Obviously infant formula is given to infants to increase their energy uptake, via the absorption of its components (fat, carbohydrates, etc.).

The subject-matter of claims 1-11 is not new over D5.

2.4 Novelty in view of D6

Prior art D6 discloses a nutritional formula comprising minerals, such as calcium (from Ca-caseinate), maltodextrin (= "edible additive") and about 15% of a fat mixture based on milk fat (41% milk fat), see claim 19 and related claim 9 of D6. An objective of D6 is to provide a formula for adequate growth and development to nursing infants and to prevent and treat certain diseases in adults (see col. 9, lines 54 - 57). The fatty acids in the formula are similar to those in human milk (see col. 10, l. 1-4).

The subject-matter of claims 1-11 is not new over D6.

2.5 Novelty in view of D7

Prior at D7 presents "Betapol", a lipid for use in infant formulas (= food article for infants, see present claim 11). It has properties resembling the human milk fat. It provides better fatty acid (C16:0) and Calcium absorption. Improved calcium absorption is known to prevent osteoporosis (see, for example, D3 or D4)

Present claims 1,4,9-11 are not new over D7.

2.6 Novelty in view of D8

Document D8 was published on the Internet on July 4, 2003. It teaches that InFat (Enzymotec), as part of an infant formula (= food article for infants, see present claim 11), will increase baby's energy and calcium "intake". It is described how InFat is designed to have properties closely related to human milk fat: high level of palmitic acid in the beta position of the triglyceride. Improved calcium absorption is known to prevent osteoporosis (see, for example, D3 or D4).

Present claims 1,4,9-11 are not new over D8.

3 Inventive step (Art. 33(3) PCT)

Inventive step of the subject matter of claims 1 to 12 will be assessed (in a possible national examination phase) once the corresponding subject matter is presented in claims, which fulfil the requirement of Art. 33(2) PCT.

An argumentation based on the 'problem-solution' approach would be helpful.

4 Clarity

Claim 1 does not fulfil the requirements of Art. 6 PCT. The extend of the invention relative to the prior art, or possible future development is not clear because:

4.1 Claim 1 is defined by a lipid not inhibiting and/or enhancing mineral absorption and intake.
In order to tell whether something is enhanced or not a reference to compare it to is needed. This reference is not clear, it may be the dietary ingredient without the lipid, or with another lipid or something else).

4.2 Claim 1 is aiming at defining a claim by a "result-to-be-achieved": enhance mineral absorption and intake, rather than by defining the essential features of the invention necessary for achieving that result (see also, for example, Guidelines for examination in the EPO: part D, chapter III, point 4.7).

4.3 The expression "mimetic (of human mother's milk fat)" (see claim 1). A mimetic could be interpreted as any fat suitable to replace a function of human milk fat, or as a chemical copy of human milk fat, or any solution in-between. Consequently claim 1 does not fulfil the requirement of Art. 6 PCT.

4.4 The expression "associated with" (claim 5) is vague.
Yes, it is acknowledged, that the expression '(a medical status/illness is) associated with (a deficiency or other irregularity)' in used the medical field.

Still, the expression "associated with" is not clear and precise enough to define the extend of a patentable claim (Art. 6 PCT), because it can be interpreted in various different ways, such as "caused by", or "linked to" or "(usually) occurring together" or "believed to have an impact on" or in other ways.

5 Industrial applicability

Industrial applicability for claims 1-12 is acknowledged by their indicated use as dietary ingredients, supplement and/or food article.

In order to facilitate examination of conformity of any amendments (in a possible national examining phase) with the requirements of Art. 28 (2) and 41 (2) PCT respectively the corresponding national Articles, the applicant is requested to clearly identify all amendments, whether there are amendments by addition, replacement, combination (e.g. of claims) or deletion.
The applicant should indicate in detail the passages in the application as **originally** filed, on which these amendments are based on.